EXPLANATORY STATEMENT

National Health Act 1953

National Health (Supplies of out-patient medication) Amendment Determination 2023

PB 134 of 2023

Authority

Subsection 84BA(2) of the *National Health Act 1953* (the Act) provides that the Minister must determine the amount that will be taken to have been paid to a public hospital for supplies of out-patient medication for the relevant entitlement period for the purposes of the Pharmaceutical Benefits Scheme (PBS) patient safety net threshold.

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

This instrument makes a minor amendment to the *National Health (Supplies of out-patient medication) Determination 2019 (No. 2)* (PB 110 of 2019) (the determination). In particular, this instrument updates the maximum value of the supply of out-patient medication to a person who is a general patient and who is not a holder of a concession card.

Background

Part VII of the Act regulates when benefits will be paid by the Commonwealth in respect of drugs and medicinal preparations that are listed on the PBS. As such, it is the legislative basis by which the Commonwealth provides reliable, timely and affordable access to a wide range of medicines to Australians.

Division 1A of Part VII of the Act provides for a safety net scheme in relation to pharmaceutical benefits. The safety net scheme is designed to provide financial protection for those patients and their families who require a large number of pharmaceutical benefits.

Subsection 84(1) of the Act defines *out-patient medication* as a drug or medicinal preparation supplied through the out-patient department of a public hospital. A drug or medicinal preparation that is supplied by a public hospital as out-patient medication may or may not be a pharmaceutical benefit under Part VII of the Act.

Subsection 84BA(1) of the Act provides that the purpose of section 84BA is to make provision so that account may be taken of payments made by a person to a public hospital authority for supplies of out-patient medication, when it is being ascertained, for the purpose of Part VII of the Act, whether the person is eligible to be issued with a concession card or an entitlement card.

Subsection 84BA(2) of the Act provides that prior to the commencement of the relevant entitlement period (a calendar year), the Minister must determine in writing the amounts that

will be taken to have been paid to a public hospital for supplies of out-patient medication made by a hospital during the relevant entitlement period.

Subsection 84BA(3) of the Act provides that, in making a determination, the Minister may determine:

- a) different amounts in respect of a supply of out-patient medication, having regard to the State or Territory in which the hospital supplying the medication is situated; and
- b) different amounts in respect of supplies made to:
 - i. concessional beneficiaries and their dependants (within the meaning of subsection 84(4) or (7) of the Act),
 - ii. holders of a concession card; and
 - iii. general patients (other than holders of a concession card).

This amending determination updates the maximum value of the supply of out-patient medication to a person who is a general patient and who is not a holder of a concession card from \$24.00 to \$25.30.

Consultation

Historically, the Department of Health and Aged Care has consulted with state and territory health departments through the Highly Specialised Drugs Working Party (HSDWP). The HSDWP was a working party of the Australian Health Ministers' Advisory Council (AHMAC) and was made up of representatives from each state and territory health department and the Commonwealth. This Working Party has now been discontinued as a second tier committee of the Hospitals Principal Committee on recommendations endorsed by AHMAC.

Through the HSDWP, the state and territory health departments agreed to the value of out-patient medication being 80% of the general co-payment each year, excluding hospitals which are in Queensland or participating in the Pharmaceutical Reform Arrangements.

State and territory health departments have been provided with the new maximum value of the supply of out-patient medication to a person who is a general patient and who is not a holder of a concession card and no additional comments have been received.

Commencement

This instrument commences on 1 January 2024.

Details of the instrument are set out in the **Attachment**. This instrument is a legislative instrument for the purpose of the *Legislation Act 2003*.

Details of the National Health (Supplies of out-patient medication) Amendment Determination 2023

1 Name

This section provides that the name of this instrument is the *National Health (Supplies of out-patient medication) Amendment Determination 2023*. The instrument can also be cited as PB 134 of 2023.

2 Commencement

This section provides that this instrument commences on 1 January 2024.

3 Authority

This section provides that the instrument is made under section 84BA of the *National Health Act 1953*.

4 Schedules

This section provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Supplies of out-patient medication) Determination 2019 (No 2) (the determination)

1 Section 8(1)

This section repeals the maximum value of the supply of out-patient medication to a person who is a general patient and who is not the holder of a concession card, which is currently \$24.00. This section replaces the amount of \$24.00 with \$25.30.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Supplies of out-patient medication) Amendment Determination 2023 (PB 134 of 2023)

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

This legislative instrument is made pursuant to subsection 84BA(2) of the *National Health Act 1953*, which determines the amounts that will be taken to have been paid to a public hospital for supplies of out-patient medication.

This instrument makes an amendment to the *National Health (Supplies of out-patient medication) Determination 2019 (No. 2)* (PB 110 of 2019) (the determination). In particular, this instrument updates the maximum value a general patient pays for out-patient medications.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access to medicines.

This legislative instrument specifies what will be taken to have been paid to a public hospital for supplies of out-patient medication for the purposes of the PBS patient safety net threshold.

The safety net scheme is designed to provide financial protection for those patients and their families who require a large number of pharmaceutical benefits.

Conclusion

This legislative instrument is compatible with human rights because it advances the protection of human rights.

Nikolai Tsyganov Assistant Secretary Pricing and PBS Policy Branch Technology Assessment and Access Division Department of Health and Aged Care